6.0 510(K) SUMMARY

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Submitter's Name and Address	ConforMIS Inc. 28 Crosby Drive Bedford, MA 01730
Establishment Registration Number	3004153240 3009844603
Date of Summary	November 19, 2013
Contact Person	Amita S. Shah, Senior Vice President, Regulatory and Quality Affairs
Telephone Number	(781) 345-9164
Fax Number	(781) 345-0147
Name of the Device	ConforMIS iTotal® Cruciate Retaining Knee Replacement System
Common or Usual Name	Cruciate Retaining Total Knee Replacement System
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	21 CFR 888.3560
Device Classification	Product Code: JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Contrained, Cemented, Polymer/Metal/Polymer OIY – Prosthesis, Knee, Patellofemorotibial, Semi-Contrained, Cemented, Polymer + Additive/Metal/Polymer +Additive OOG – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices. Indicated to include guiding alignment, making or establishing cuts, selecting, sizing, attaching, positioning or orienting implant components.

510(k) Summary continued	
Indications for Use	The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis. The Indications for Use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants. • Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. **This implant is intended for cemented use only**
Identification of the Legally Marketed Devices (Predicate Devices)	ConforMIS iTotal CR Knee Replacement System (KRS) Device Class: II Product Code: JWH, OOG, OIY Regulation Number: 21 CFR 888.3560 510(k) number: K131467, K131019, K122870

510(k) Summary continued	
Device Description	The iTotal Cruciate Retaining Knee Replacement System (hereafter referred to as the "iTotal CR KRS") is a patient specific tricompartmental faceted posterior cruciate ligament (PCL) retaining knee replacement system. The iTotal CR KRS is a semi-constrained cemented knee implant which consists of a femoral, tibial and patellar component. Using patient imaging (either CT or MR scans) and a combination of proprietary and off the shelf software a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The femoral component is manufactured from cobalt chromium molybdenum (CoCr) alloy. The tibial component includes a metal tray manufactured from CoCr alloy and either one or two polyethylene inserts. The polyethylene inserts may be manufactured from either UHMWPE or a highly cross-linked Vitamin E infused polyethylene (iPoly XE™) The patellar component is also manufactured from either UHMWPE or from a highly cross-linked Vitamin E infused polyethylene (iPoly XE). For user convenience, and similar to the predicate iTotal CR KRS, accessory orthopedic manual surgical instruments designed for use with the modified iTotal CR KRS are provided to assist with implantation. The ancillary instruments are provided sterile and for single-use only. These patient specific instruments are provided to assist in the positioning of total knee replacement components intra-operatively and in guiding the cutting of bone. The function and general design features of the patient specific ancillary instruments remain similar to those described in the predicate iTotal CR 510(k)s (**K131467, K131019 and K122870)**.

510(k) Summary continued	

Substantial Equivalence	The product subject of this premarket notification is substantially equivalent in design and functionality to the iTotal Cruciate Retaining Knee Replacement System (**K131467** cleared July 18, 2013, **K131019** cleared May 24, 2013, and **K122870** cleared January 14, 2013). The proposed femoral components will be manufactured by an additive manufacturing process using CoCr alloy in a powdered form.
	
	The following non-clinical laboratory testing was performed to determine substantial equivalence:
	
	• Material properties of CoCr implants manufactured by an additive manufacturing process
	  o Mechanical properties testing
	  o Physical properties testing
	• Biocompatibility Testing of implants manufactured by the additive manufacturing process
	• Performance testing of femoral implants manufactured through the additive manufacturing process
	  o Fatigue testing
	  o Contact stress/area testing
	
	All testing has demonstrated the device is substantially equivalent to the predicate devices.

510(k) Summary continued:
Device Comparison

Characteristic	iTotal CR KRS with femoral component manufactured via an additive manufacturing process (This submission)	Predicate iTotal CR KRS (K131467, K131019 and K122870)
Indication for Use	The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis. The indications for use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants. • Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans The implant is intended for cemented use only	The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis. The indications for use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bi-compartmental implants. • Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans The implant is intended for cemented use only
Intended for Cemented Use Only	Yes	Yes
Product Classification	21 CFR 888.3560 (JWH)	21 CFR 888.3560 (JWH)
Design	Knee joint patellofemorotibial semi –constrained cemented prosthesis	Knee joint patellofemorotibial semi –constrained cemented prosthesis
Tibial Implant	• Configuration: Metal Backed Tibial Implant • Tibial Insert UHMWPE or Vitamin E infused highly cross-linked UHMWPE • Single or Dual inserts • Insert sizes:6-16mm • Profile: patient specific	• Configuration: Metal Backed Tibial Implant • Tibial Insert UHMWPE or Vitamin E infused highly cross-linked UHMWPE • Single or Dual inserts • Insert sizes:6-16mm • Profile: patient specific

Femoral Implant	• CoCr - cast, wrought or additive manufacturing process • Patient specific	• CoCr - cast or wrought material • Patient specific
Patella Implant	• UHMWPE or • Vitamin E infused highly cross-linked UHMWPE	• UHMWPE or • Vitamin E infused highly cross-linked UHMWPE
Instrumentation	Patient specific Nylon jigs	Patient specific Nylon jigs
Principle of Operation	Cemented use Fixed Bearing Design	Cemented use Fixed Bearing Design
Posterior Cruciate Ligament (PCL) Sparing	Yes	Yes
Patient-Matched	Yes	Yes
Packaging	Device components are individually double pouched using Tyvek® /film pouches which are sealed and labeled	Device components are individually double pouched using Tyvek® /film pouches which are sealed and labeled
Sterility Method/ Assurance Level	VHP Gas Plasma $1x10^{-6}$	VHP Gas Plasma $1x10^{-6}$
Initial Shelf-Life	6 months	6 months
Labeled Non-pyrogenic	No	No

510(k) Summary continued

Description and Conclusion of Testing

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. Testing on the femoral components manufactured from an additive manufacturing process is outlined below:

- Material properties tests
- Mechanical properties testing
- Biocompatibility tests
- Contact area/contact stress testing
- Fatigue testing of femoral implant

Test results demonstrated that the device is safe and can be considered substantially equivalent to the predicate device for the intended use.

Safety and Performance

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. The testing demonstrated that the device is safe for its intended use and can be considered substantially equivalent to the predicate devices. Clinical data is not necessary to demonstrate substantial equivalence.

Conclusion

Based on the testing conducted, it is concluded that the iTotal Cruciate Retaining Knee Replacement System with femoral components made from an additive manufacturing process is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (**K131467, K131019 and K122870)**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

ConforMIS, Incorporated
Amita Shah
Senior Vice President, Regulatory and Quality Affairs
28 Crosby Drive
Bedford, Massachusetts, USA

Re: K133560
Trade/Device Name: iTotal CR Knee Replacement System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY, OOG
Dated: March 3, 2014
Received: March 4, 2014

Dear Ms. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133560

Device Name: iTotal CR Knee Replacement System

Indications for Use:

The iTotal® CR Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices